K132237

510(k) SUMMARY

CONTACT

Emily Ziegler
Scientist I
Gen-Probe Prodesse, Inc.
20925 Crossroads Circle
Waukesha, WI 53186

AUG 2 6 2013

NAME OF DEVICE

Trade Name:	Prodesse® ProFAST®+ Assay
Regulation Number:	21 CFR 866.3332
Product Code:	OQW, OOI
Classification Name:	Nucleic acid amplification assay for detection and differentiation of Influenza A Virus Subtypes: A/seasonal H1, A/seasonal H3, and A/2009 H1N1 Influenza Virus

PREDICATE DEVICE

K101855, ProFAST™+ Assay

INTENDED USE

The Prodesse® ProFAST®+ Assay is a multiplex Real Time RT-PCR *in vitro* diagnostic test for the qualitative detection and discrimination of seasonal Influenza A/H1, seasonal Influenza A/H3 and 2009 H1N1 Influenza viral nucleic acids isolated and purified from nasopharyngeal (NP) swab specimens from human patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors. This Assay targets conserved regions of the Hemagglutinin (HA) gene for seasonal Influenza A/H1, seasonal Influenza A/H3 and 2009 H1N1 Influenza Virus, respectively. This Assay is not intended to detect Influenza B or Influenza C Viruses.

A negative ProFAST+ Assay result is a presumptive negative result for Influenza A. These results should be confirmed by an FDA cleared nucleic acid-based test (NAT) detecting Influenza A.

Negative results do not preclude Influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions.

If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

PRODUCT DESCRIPTION

The ProFAST+ Assay enables detection and discrimination of Influenza A Virus subtypes: seasonal A/H1, seasonal A/H3, and 2009 H1N1 and internal control nucleic acid. Nasopharyngeal swab specimens are collected from patients with signs and symptoms of a

respiratory infection using a polyester, rayon or nylon tipped swab and placed into viral transport medium.

A Universal Internal Control (UIC) is added to each sample prior to nucleic acid isolation to monitor for inhibitors present in the specimens. The isolation and purification of the nucleic acids is performed using either a MagNA Pure LC Instrument (Roche) and the MagNA Pure Total Nucleic Acid Isolation Kit (Roche) or a NucliSENS® easyMAG™ System (bioMérieux) and the Automated Magnetic Extraction Reagents (bioMérieux).

The purified nucleic acids are added to ProFAST+ Supermix along with enzymes included in the ProFAST+ Assay Kit. The ProFAST+ Supermix contains oligonucleotide primers and target-specific oligonucleotide probes. The primers are complementary to highly conserved regions of the Hemagglutinin (HA) gene for seasonal influenza A/H1, seasonal influenza A/H3 and 2009 H1N1 Influenza Virus. The probes are dual-labeled with a reporter dye attached to the 5'-end and a quencher dye attached to the 3'-end (see table below).

Analyte	Gene Targeted	Probe Fluorophore	Absorbance Peak	Emission Peak	Instrument Channel
Seasonal H1 Influenza A	*Hemagglutinin*	FAM	495 nm	520 nm	Seasonal H1 Influenza A
Seasonal H3 Influenza A	*Hemagglutinin*	CAL Fluor Orange 560	540 nm	561 nm	Seasonal H3 Influenza A
2009 H1N1 Influenza Virus	*Hemagglutinin*	CAL Fluor Red 610	595 nm	615 nm	2009 H1N1 Influenza Virus
Universal Internal Control	*N/A*	Quasar 670	647 nm	667 nm	Universal Internal Control

Reverse transcription of the RNA in the sample into complementary DNA (cDNA) and subsequent amplification of DNA is performed in a Cepheid SmartCycler® II instrument. In this process, the probe anneals specifically to the template followed by primer extension and amplification. The ProFAST+ Assay is based on Taqman chemistry, which utilizes the 5' – 3' exonuclease activity of the Taq polymerase to cleave the probe thus separating the reporter dye from the quencher. This generates an increase in fluorescent signal upon excitation from a light source. With each cycle, additional reporter dye molecules are cleaved from their respective probes, further increasing fluorescent signal. The amount of fluorescence at any given cycle is dependent on the amount of amplification products present at that time. Fluorescent intensity is monitored during each PCR cycle by the SmartCycler II instrument.

DEVICE COMPARISON

The modified ProFAST+ Assay differs from the current kit in the following ways:

- Outsourcing of internal control stock manufacturing leading to a change in control vector;
- Universal Internal Control, consisting of an RNA *in vitro* transcript and a DNA plasmid, incorporated into the kit;
- The 1:10 dilution step of the positive control performed by customers has been removed;
- Additional reactivity claims for Influenza A/Indiana/10/2011 (H3N2v).

The labeling was updated accordingly to incorporate the modifications listed above.

SUBSTANTIAL EQUIVALENCE

1. The Intended Use, Warnings or Precautions, and Contraindications of the modified device as described in the labeling have not changed.
2. The modifications detailed in the table below has not had any effect or caused any changes to the fundamental scientific technology of the device.

Modification	Potential Impact of Modification	Verification/Validation Result
Outsourcing of internal control leading to minor changes in sequence	Modification of the internal control may affect the ability of the device to detect the target organisms. Additionally, it may change the clinical performance of the ProFAST+ Assay.	The UIC did not affect the ability of the ProFAST+ Assay to detect target organisms at the limit of detection as evinced by the results of Analytical Sensitivity, IC Interference, Extractor Equivalency, and Sample Stability studies. Additionally, the results of a retrospective clinical comparison study demonstrated the modified ProFAST+ Assay with UIC continues to meet the performance claims for the current ProFAST+ Assay.
Incorporation of a Universal Internal Control, containing both RNA and DNA internal control sequences.		
Positive control provided "at use" concentration, no dilution is necessary.	Changes in the testing concentration may affect the performance of the positive control in terms of stability or ability to detect global assay failures.	A Positive Control Effectiveness Study demonstrated the positive control's continued ability to monitor for global assay failures at the increased testing concentration.
H3N2v Reactivity Claims	NA	Results of the Reactivity Study demonstrated the ability of the ProFAST+ Assay to detect A/Indiana/10/2011 (H3N2v) nucleic acids at concentrations near the limit of detection of the assay.

Although this test has been shown to detect influenza A/ Indiana/10/2011 (H3N2v) virus cultured from positive human respiratory specimens, the performance characteristics of this device with clinical specimens that are positive for H3N2v influenza virus have not been established.

3. Verification and validation studies performed demonstrated that all clinical and analytical performance/functionality remains unchanged from the previous device.
4. The appropriate Design Control activities were performed;
    a. A Risk Analysis was performed and did not raise any new concerns of safety and efficacy associated with the modifications.
    b. A declaration of conformity with design controls has been submitted.

The modified ProFAST+ Assay is substantially equivalent to the current legally marketed device, ProFAST+ Assay.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 26, 2013

Emily Ziegler
Scientist I
Gen-Probe Prodesse, Inc.
20925 Crossroads Circle
Waukesha, WI 53186

Re: K132237

Trade/Device Name: Prodesse® ProFAST®+ Assay
Regulation Number: 21 CFR 866.3332
Regulation Name: Reagents for detection of specific novel influenza A viruses
Regulatory Class: Class II
Product Code: OQW, OOI
Dated: July 16, 2013
Received: July 30, 2013

Dear Ms. Ziegler:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Sally A. Hojvat -S

Sally Hojvat, M.Sc., Ph.D.
Director, Division of Microbiology Devices
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number (if known): K132237

Device Name: Prodesse® ProFAST®+ Assay

Indication for Use:

The Prodesse® ProFAST®+ Assay is a multiplex Real Time RT-PCR *in vitro* diagnostic test for the qualitative detection and discrimination of seasonal Influenza A/H1, seasonal Influenza A/H3 and 2009 H1N1 Influenza viral nucleic acids isolated and purified from nasopharyngeal (NP) swab specimens from human patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors. This Assay targets conserved regions of the Hemagglutinin (HA) gene for seasonal Influenza A/H1, seasonal Influenza A/H3 and 2009 H1N1 Influenza Virus, respectively. This Assay is not intended to detect Influenza B or Influenza C Viruses.

A negative ProFAST+ Assay result is a presumptive negative result for Influenza A. These results should be confirmed by an FDA cleared nucleic acid-based test (NAT) detecting Influenza A.

Negative results do not preclude Influenza virus infection and should not be used as the sole basis for treatment or other patient management decisions.

If infection with a novel Influenza A virus is suspected based on current clinical and epidemiological screening criteria recommended by public health authorities, specimens should be collected with appropriate infection control precautions for novel virulent Influenza viruses and sent to state or local health department for testing. Viral culture should not be attempted in these cases unless a BSL 3+ facility is available to receive and culture specimens.

Prescription Use __X__ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health (CDRH)

Tamara V. Feldblyum -S
2013.08.26 16:13:17 -04'00'